5. 510(K) SUMMARY

HEMODIA ARTHROSCOPY PUMP TUBE SETS - 510(k) Summary

OWNER:	Hemodia S.A.S. 85 du Chêne Vert, 31670 Labège FRANCE Tel: +33 5 61 00 71 81 – Fax: +33 5 61 00 47 40 remi.teuliere@hemoda.com
Contact:	Mr. Rene van de Zande, President & CEO Emergo Group, Inc. Phone: 512.327.9997 Fax: 512.327.9998 usagent@emergogroup.com
Date Summary Prepared:	October 15th 2013
Device Trade Name:	HEMODIA ARTHROSCOPY PUMP TUBE SETS
Common Name:	Arthroscopic pump tube sets
Classification Name:	Arthroscope
Classification Code:	21 CFR Part 888.1100 87 Orthopedic Product Code: HRX
Equivalent Device(s):	• OrthoConcept (FMS 4+ & disposables) K925160 • FMS K954465 (FMS DUO ® + & disposables) • FMS K951843 (REF. 4102CV INTERMEDIARY TUBING, REF. 4509CV STERILE ZONE KIT) • FMS K002040 (FMS SOLO® & disposables)
Device Description:	HEMODIA ARTHROSCOPY PUMP TUBE SETS (HATS) are tube sets that deliver irrigation fluid both to and from the pump and to and from the operative site during arthroscopic procedures.
Intended and Indications for Use:	The device intended to be used in conjunction with the FMS/Depuy/Mitek arthroscopic pump systems and delivers both irrigation fluid to and from the pump and to and from the operative site during arthroscopic procedures.
Technological Characteristics	The TUBE SETS are similar in material (including packaging material), design, function, and application to the single use predicate devices. The device is not self-powered but uses the same energy source (pumps) as the predicate devices. The technological characteristics are the same as the predicate device.
Performance Data:	Performance testing was performed to demonstrate equivalence to the tube sets not the hardware referenced in the predicate devices. Hemodia's testing included bench testing for functional equivalence, tube set leak testing under pressure, bond strength. These test support that the design, packaging, sterilization &

	labeling of the TUBE SETS are substantially equivalent to currently marketed single use predicate devices.
Clinical Performance Data:	A clinical evaluation report was undertaken, supporting that clinical testing was not necessary to support substantial equivalence to predicate devices.
Substantial Equivalence summary:	Based on the comparison of the intended use, the technological characteristics and performance data, Hemodia S.A.S has determined that the proposed HEMODIA ARTHROSCOPY PUMP TUBE SETS (HATS) are substantially equivalent to the currently marketed single use predicate devices, OrthoConcept (FMS 4+ & disposables) K925160, FMS K954465 (FMS DUO ® + & disposables) FMS K951843 (REF. 4102CV INTERMEDIARY TUBING, REF. 4509CV STERILE ZONE KIT), FMS K002040 (FMS SOLO® & disposables). HATS are tube sets that deliver irrigation fluid both to and from the pump and to and from the operative site during arthroscopic procedures. The proposed devices have the same intended use, are similar in material (including packaging material), same sterilization method, design, function, and application to the single use predicate devices. The device is not self-powered but use the same energy source (pump) as the predicate device. Performance testing demonstrates equivalence to the predicate single use tube sets. Hemodia included bench testing for functional equivalence, tube set leak testing under pressure, bond strength. These test support that the design, packaging, sterilization & labeling of the TUBE SETS are substantially equivalent to currently marketed single use predicate devices. Any differences between the HATS tube sets and the predicates single use sets are considered minor and do not raise questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

Hemodia S.A.S
% Mr. Dave Yungvirt
Parmalink Technical Group, LLC
20 F Street NW, Suite 700
Washington, DC 20001

November 1, 2013

Re: K132883
Trade/Device Name: HEMODIA ARTHROSCOPY PUMP TUBE SETS
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: October 14, 2013
Received: October 18, 2013

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number if known: N/A

Device Name: HEMODIA ARTHROSCOPY PUMP TUBE SETS

Indications for use:

The device intended to be used in conjunction with the FMS/Depuy/Mitek arthroscopic pump systems and delivers irrigation fluid both to and from the pump and to and from the operative site during arthroscopic procedures.

Prescription Use _✔_ Use _____ (Per 21 CFR 801 Subpart D) Subpart C)	AND/OR	Over-the-Counter (Per 21 CFR 807

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Long H. Chen -A for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K132883